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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,047	10/20/2005	Tadao Saito	SPO-120	9241
23557 7590 07/16/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER				
OLSON, ERIC				
ART UNIT		PAPER NUMBER		
1623				
MAIL DATE		DELIVERY MODE		
07/16/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/522,047

**Applicant(s)**

SAITO ET AL.

**Examiner**

ERIC S. OLSON

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2009.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-11 and 15-22 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 7-11 and 15-22 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/5508)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

### **Detailed Action**

This office action is a response to applicant's communication submitted April 22, 2009 wherein claims 7, 11, 17, and 22 are amended. This application is a national stage application of PCT/JP03/09324, filed July 23, 2003, which claims priority to foreign applications JP2002-213305, filed July 23, 2002, and JP2003-050739, filed February 27, 2003.

Claims 7-11 and 15-22 are pending in this application.

Claims 7-11 and 15-22 as amended are examined on the merits herein.

Applicant's amendment, submitted April 22, 2009, with respect to the rejection of instant claims 17, 18, and 21 under 35 USC 112, first paragraph, for lacking enablement for a method of preventing disease, has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to no longer recite preventative methods. Therefore the rejection is withdrawn.

Applicant's amendment, submitted April 22, 2009, with respect to the rejection of instant claims 7-10, 15-19, and 21 under 35 USC 103(a) for being obvious over Bijsma et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that at least 90% of the total hydroxyl groups in the dextran be phosphorylated. Therefore the rejection is withdrawn.

Applicant's amendment, submitted April 22, 2009, with respect to the rejection of instant claim 22 under 35 USC 103(a) for being obvious over Bijlsma et al. in view of Tarelli et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that at least 90% of the total hydroxyl groups in the dextran be phosphorylated. Therefore the rejection is withdrawn.

Applicant's amendment, submitted April 22, 2009, with respect to the rejection of instant claims 11 and 20 under 35 USC 103(a) for being obvious over Bijlsma et al. in view of Suzuki et al. R4 in view of Sacco et al., has been fully considered and found to be persuasive to remove the rejection as the claims have been amended to require that at least 90% of the total hydroxyl groups in the dextran be phosphorylated. Therefore the rejection is withdrawn.

Applicant's amendment, submitted April 22, 2009, necessitates the following new grounds of rejection:

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-11 and 15-22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant's amendment submitted January 8, 2007 with respect to the aforementioned claims has been fully considered and but is deemed to insert **new matter** into the claims since the specification as originally filed does not provide support for phosphorylated dextran in which at least 90% of the hydroxyl groups are phosphorylated. As the instant specification as filed contains no description of these dextran species the specification as originally filed does not provide support for the subject matter of instant claims 7-11 and 15-22. See *in re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972).

Specifically, dextran is a 1,6- linked glucose polysaccharide as illustrated below:

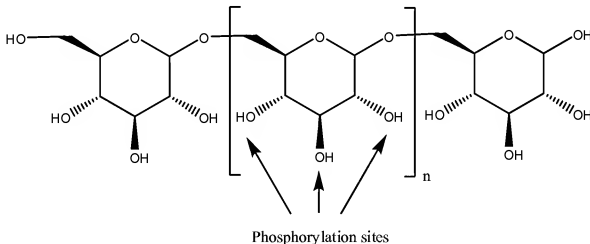


Figure 1 - Structure of Dextran

As shown in figure 1, dextran has three phosphorylation sites per monosaccharide subunit, the secondary hydroxyl groups at the 2-O, 3-O, and 4-O positions of the glucose subunit. A dextran molecule possesses only one 1-OH and one 6-OH group available for phosphorylation at the reducing and non-reducing ends of the

molecule. Therefore a dextran molecule that is phosphorylated at 90% of the free hydroxyl groups, such as those claimed, will have at least 2.7 phosphate groups per monosaccharide on average. As the molecular formula of a fully phosphorylated saccharide subunit is  $C_6H_{16}O_{14}P_3$ , for a molecular weight of 405 per saccharide, a fully phosphorylated dextran molecule will comprise about 23.0% phosphorus by weight, and a 90% phosphorylated dextran will comprise about 20.6% phosphorus.

The specification as originally filed makes no mention of dextrans in which 90% or more of the total hydroxyl groups are phosphorylated. P. 5 lines 29-36 of the specification indicate that the phosphorylation site of the dextrans of the present invention are typically at the 6-OH group of dextran. Furthermore, p. 10 lines 1-12 describe the present invention as improved over prior art phosphorylation methods in that almost all hydroxyl groups at position six can be phosphorylated. As dextran possesses only one 6-OH group per molecule (at the non-reducing end) phosphorylating all of the 6-OH groups will not produce anything close to phosphorylation of 90% of the hydroxyl groups. Although branching of the dextran could increase the number of free 6-OH groups by one per branch point, it would not produce a dextran in which 90% of the free OH groups are 6-OH groups. Even in the extreme case of a dendrimer wherein all of the non-terminal sugars are branched at all of the 2-O, 3-O, and 4-O positions, so that there are no free OH groups except at the terminal sugar units, the resulting molecule would still possess one free 2-OH, 3-OH, 4-OH, and 6-OH group at each terminal non-reducing subunit, for only 25% 6-OH groups.

Furthermore, figure 2 of the drawings discloses phosphorus contents of various products produced by the inventive phosphorylation method. The highest phosphorus content achieved is 1.7%, which would correspond to less than 10% of the free hydroxyl groups being phosphorylated. Examples 1-2, pp. 14-15 of the specification further disclose an analysis using anion exchange chromatography showing that about 100% of the total phosphorylated dextran adsorbs to an anion exchange column. This result merely shows that substantially all of the dextran is phosphorylated at one or more hydroxyl groups, and gives no indication that the dextran is phosphorylated at 90% of the free OH groups.

With regard to the prior art phosphorylation of dextrans, Suzuki et al. (reference of record in PTO-1449 submitted October 26, 2005) discloses phosphorylation of dextran by a method similar to that used by Applicant, and upon which the specification indicates that Applicant's phosphorylation method is based. The highest phosphorus content achieved for phosphorylation of free dextran, as opposed to acylated dextran (entry DP-II in table 1, p. 224 of Suzuki et al.) is 18.3%, which corresponds to a phosphorylation degree of about 79.6% of the hydroxyl groups phosphorylated. Therefore in the absence of analytical data showing 90% or greater phosphorylation degree for the dextran phosphates produced by Applicant, there is no reason to believe that Applicant's method produces dextrans with over 90% phosphorylation either, especially in view of the aforementioned elemental analysis data of figure 2 of the instant specification.

Therefore the present amendment is seen to introduce new matter into the disclosure. As Applicant's amendment necessitated this new ground of rejection, the rejection is made **FINAL**.

### **Conclusion**

No claims are allowed in this application. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC S. OLSON whose telephone number is (571)272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone



number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric S Olson/  
Examiner, Art Unit 1623  
7/13/2009

/Leigh C. Maier/  
Primary Examiner, Art Unit 1623